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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09 677,042	09 29 2000	Yasuyuki Nozaki	07898-059001	1694

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EXAMINER

MORAN, MARJORIE A

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 11 27 2002

Please find below and or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/677,042

**Applicant(s)**

NOZAKI ET AL.

**Examiner**

Marjorie A. Moran

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on 13 September 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☐ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) 5, 7-10 and 12-15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 1-4, 6 and 11 is/are rejected.
- 7) ☐ Claim(s) 1, 3, 4 and 11 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### ***Election/Restrictions***

Applicant's election of Group I, claims 1-11 and species of "states of an individual's tissues" (species (3)) in Paper No. 5, filed 9/13/02, is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Claims 5 and 7-10 recite nonelected species and are therefore considered nonelected.

Claims 5, 7-10 and 11-15 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Invention or species, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 5.

An action on the merits of claims 1-4, 6, and 11, as they read on the elected species, follows.

### ***Information Disclosure Statement***

The IDS filed 3/4/02 has been considered.

### ***Drawings***

The drawings are objected to as set forth on Form PTO 948. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. Applicant is reminded that the objection to the drawings will not be held in abeyance.

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### ***Specification***

The abstract of the disclosure is objected to because it is more than one paragraph in length and does not appear to be directed to the subject matter of the elected claims. Correction is required. See MPEP § 608.01(b).

### ***Claim Objections***

Claims 1, 3-4, and 11 are objected to because of the following informalities. Each element or step of the method and system of claims 1 and 11 is not separated by a line indentation, as required under 37 CFR 1.75(i). See also MPEP 608.01(m) for a discussion of proper claim format. In claims 3 and 4, the phrase "become to have" is grammatically incorrect. See below for examples of suggested claim format and language. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-4 and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 recites that a "reference value determines" in line 2. A reference value is not an entity capable of performing a calculation or making a comparison, therefore it is unclear what method step applicant intends by this phrase. Applicant is advised that

merely rewriting the claim to recite that a reference value "is used to determine" whether expression patterns of different genes are identical will not overcome the indefiniteness of the claim as it will still be unclear what step (mathematical, physical?) is intended by the term "used". The examiner suggests reciting a definite method step; e.g. -- comparing expression patterns of two different genes to a reference pattern to determine...--. Applicant should note that this is an example of suggested claim format and not a suggested claim limitation. The claim should be rewritten to render clear the method step intended by applicant.

Claim 2 recites "two expression patterns of different genes" in lines 2-3. It is unclear if applicant intends --several expression patterns of two different genes-- or --an expression pattern from each of two genes-- or --two expression patterns from each of several different genes--, therefore the claim is indefinite. For purposes of further examination, the examiner interprets the claim to be reciting comparison of a reference value to a (single) expression pattern from each of two different genes to determine whether the expression patterns of the two different genes are identical.

Claims 3 and 4 each recite a step of displaying genes according to a predetermined display format, then recite a change in expression format for the displayed genes. It is unclear if the change in expression format is intended to be a method step, or is intended to be a limitation of the gene expression pattern, or is intended to be a limitation of a gene, or is intended to be a limitation of the display format, therefore the claims are indefinite. The examiner suggests rewriting each claim so that any intended method steps are recited in active, positive language, and such

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that any other claim limitations are clear; e.g. --displaying results for two or more different genes according to the predetermined display format wherein the genes are ones which....-- Applicant should note that this a suggestion ONLY for claim format and is reminded that it should be made clear, for each limitation recited, *what* applicant is intending to limit.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-2, 6, and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by PEROU et al. (PNAS (8/1999) vol. 96, pp. 9212-9217).

PEROU teaches a method and apparatus for displaying gene expression patterns of multiple genes wherein the expression patterns of the genes change according to experimental conditions and wherein a first axis represents the genes and a second axis represents experimental conditions (p. 9213, Figure 1). PEROU further teaches comparison of data from expression in different tissue states to a reference value, and "repeating" clustering such that clusters "move" along an axis by comparison

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to changing, or different reference values (e.g. Figure 3 shows different (moved) clusters based on comparison to IFN-regulated reference genes and comparison to proliferation-associated reference genes), thus claims 1 and 11 are anticipated. As the point of PEROU's experiments is comparison of expression clusters to determine whether the expression patterns of different genes are identical, claim 2 is also anticipated. PEROU teaches that the experimental conditions he uses are intended to identify gene expression patterns related to breast cancer; i.e. a "tissue state" (abstract), therefore claim 6 is anticipated.

Claims 1-4, 6, and 11 are rejected under 35 U.S.C. 102(e) as being anticipated by ZHENG et al. (US 6,263,287, filed 11/12/1998).

ZHENG teaches a method and apparatus for displaying gene expression patterns of genes related to disease (tissue) states characterized by differences in expression patterns wherein gene expression data from a plurality of genes is compared on a two-dimensional grid comprising gene and expression data, and expression patterns are compared to a reference (col. 5, line 16- col. 6, line 19 and Figure 13). ZHENG specifically teaches comparison of expression levels in different tissues or disease states (col. 7, lines 14-26), thus claims 1, 6, and 11 are anticipated. ZHENG teaches that his method and system can be used to determine if expression patterns from different genes are identical, converge or diverge (col. 15, lines 48-68 and Figure 19), thus anticipating claims 2-4.

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**Conclusion**

Claims 1-4, 6, and 11 are rejected; claims 5, 7-10, and 12-15 are withdrawn.

Claims 1, 3-4, and 11 and the abstract are also objected to.

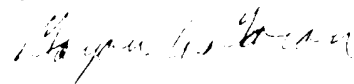
The prior art made of record and not relied upon which is considered pertinent to applicant's disclosure is WEN et al. (PNAS (1/1998) vol. 95, pp. 334-339).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marjorie A. Moran whose telephone number is (703) 305-2363. The examiner can normally be reached on Monday to Friday, 7:30 am to 4 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (703) 308-4028. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 872-9306 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to an LIE, Tina Plunkett, whose telephone number is (703) 305-3524.

MARJORIE MORAN  
PATENT EXAMINER



November 26, 2002